Pharmaceutical Manufacturer Healthcare Certification Application Checklist

Welcome to LegitScript's Application Checklist for Pharmaceutical Manufacturers! We are excited to support you on your journey toward LegitScript Healthcare Certification. This checklist has been thoughtfully designed to guide you through preparing your application with ease and clarity.

At LegitScript, we are committed to offering a certification program you can trust—one that reflects your dedication to upholding the highest standards in healthcare. As you work through the checklist, we encourage you to familiarize yourself with our Certification Standards, Terms & Conditions, and program FAQs to ensure a comprehensive understanding of our requirements.

If you have any questions about the certification process or need further assistance, our team is here to help. Please don't hesitate to reach out to us at Certification@LegitScript.com.

Thank you for choosing LegitScript—we look forward to partnering with you every step of the way on your path to certification!

Scope Considerations

☐ If your company manufactures FDA-approved products for commercial use or has submitted New Drug Applications (NDAs), your business is within scope for LegitScript certification.

    ☐ Please note that manufacturers without any FDA-approved, commercially available products or products pending approval are not eligible for certification.

Licensure and Registration

☐ Be sure to include your active Secretary of State filing number on the Business Registration tab of the LegitScript licensure template.

☐ Please be prepared to provide the active pharmaceutical manufacturer license information for *every* jurisdiction in which you operate on the applicable tab.

☐ If your business is located in the United States, please be prepared to provide proof of FDA establishment registration.

☐ Manufacturing controlled substances in the United States? Please upload a copy of your DEA Certificate(s).

☐ If you hold any additional certification, accreditation, or licensure, please be sure to provide us with that information.

☐ Does your business identify as a virtual manufacturer? If so, please provide us with your applicable virtual manufacturer license information.

☐ Please be sure to completely fill out the Products - Manufacturers tab of the LegitScript licensure template.

Legal Compliance

☐ Make sure your website's language and product offerings follow state and/or country-specific laws and regulations.

☐ Please be sure to provide us with all inspection reports from the last 5 years that were performed by a Board of Pharmacy or any other regulatory agency.

☐ Subject to discipline within the last 10 years? Please have evidence/documentation to support discipline resolutions. Please reference our Terms & Conditions - IV(d.), for examples of Disciplinary Action.

☐ Please be prepared to demonstrate how your business is compliant with the Drug Supply Chain Security Act (DSCSA) as required by the FDA if you are serving the United States.

Patient Services

☐ Have you ensured your products and services are up-to-date with regulatory requirements, and that you are not offering prohibited services or impermissible products?

☐ Please ensure advertising claims are in line with current applicable regulatory guidelines. For merchants based in the United States, this includes FDA and FTC advertising guidelines.

☐ Be prepared to demonstrate how your business is in compliance with CGMP (Current Good Manufacturing Practice) standards. This may be done by providing us with any applicable standard operating procedures you have in place.

Transparency

☐ When uploading an image of your domain's Whois information, is the contact information depicted transparent and accurate?

☐ Please be sure your privacy protection is removed so the image displays the following Whois information: registrant name, registrant organization (if applicable), registrant address, registrant phone number, and registrant email address.

☐ Is your website still under development/expecting updates? Please prepare wireframes/screenshots and the expected timeframe of completion.

☐ Please create a test patient account and provide us with a username and password to access your patient/client portal.

Affiliates

☐ Ensure affiliates or affiliations with your business are compliant and operating legally.

    ☐ Affiliates are any individual, business, or entity who previously, currently, or is expected to have a commercial and/or professional relationship with the applicant organization or its principals.

        ☐ Common barriers can include affiliations with the sale of CBD ingestible products, the sale of unapproved drugs ex: impermissible peptides or bulk drug substances, or affiliates with severe disciplinary history.

☐ Are your manufacturing operations outsourced to a contract manufacturer? If so, please be aware that the contract manufacturer must be approved by LegitScript. Approval can be obtained through one of the following two pathways:

    ☐ The applying merchant may respond to compliance questions and provide licensure on behalf of the contract manufacturer. For more information about this requirement, please contact certification@legitscript.com.

    ☐ The contract manufacturer may submit their own application for LegitScript certification. Please note that the outcome of their compliance review may affect your own certification, if there is an active partnership.

☐ Remember, all applicable business models promoted on the domain submitted for certification, must also be certified per our Terms & Conditions - VI(d.)

Questions? Email our team at Certification@LegitScript.com